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Comments by the City-County Board of Health for Lincoln County to EPA's Proposed  
Plan to Address Environmental Cleanup at  
Operable Units 1 and 2  
January, 2010

Introduction:

The City-County Board of Health for Lincoln County ("Board of Health") presents the following comments to the U.S. Environmental Protection Agency's (EPA's) Proposed Plans (PPs) for Operable Unit (OU) 1 and OU 2 of the Libby Asbestos Superfund Site. The Board of Health would like to acknowledge the Libby Area Technical Advisory Group (LATAG) for its input and assistance.

Comment 1:

The Libby Asbestos Site has had documented public health impact orders of magnitude above that of any other federal Superfund Site. Moreover, the risks to residents of Libby and visitors to the area due to exposure to Libby amphibole (LA) asbestos pose unique threats due to the multiple pathways (known and unknown) of exposure. Residents and workers in Libby may be exposed through inhalation of LA in outdoor ambient air, inhalation while engaged in outdoor activities that disturb LA in soil (e.g., mowing, raking, digging), inhalation of LA indoors at home or at work, and in ways not yet understood. Because of the multiple pathways of exposure, the risks of cancer and non-cancer adverse health effects must be reduced as low as possible in all OUs.

As more fully described in the following comments, while helpful to reduce known risks and a step in the right direction, the PPs for OU 1 and 2 cannot with confidence be said to provide the protection of public health, safety, welfare, and the environment required under federal and state law. At best, the PPs describe an interim remedy that, following additional study and analysis described in the following comments, may be deemed to be final or may be required to be augmented. Any Record of Decision (ROD) based on the PPs should term the proposed remedies as interim and provide a detailed course of study and analysis to guide the future evaluation of that remedy as either final or needing augmentation.

Comment 2:

The Board of Health understands that the fundamental remedy selected for both OU 1 & 2 is not complete removal of the LA asbestos, but severance of the pathways of exposure. Before such a remedy can be successfully designed and/or implemented, or said to be effective in protecting public health safety, welfare, and the environment, all the pathways of exposure must be known and understood. However, the relationship between LA contamination of soil and indoor dust to airborne concentrations of LA (and hence exposure) is poorly understood. That is, the results of EPA's activity-based sampling at residential and commercial properties in Libby in 2007 and 2008 did not show a conclusive link between media concentrations and airborne exposures. Further research and testing is needed to better define this relationship before a final remedy can be determined for any OU.

Comment 3:

EPA conducted activity-based sampling at residential and commercial properties in Libby in 2007 and 2008. Preliminary review of these results indicates that the current removal action level for LA in soil is likely to be revised to a lower concentration. Additional activity-based sampling consistent with comments 4 and 5 below, together with reliable sampling and analytical methods for LA in solid matrices (soils and dust) and air, should provide for a better understanding of the relationship between LA contamination of soil and indoor dust to airborne concentrations of LA. Exposure parameters of Central Tendency Exposure (CTE) and Reasonable Maximum Exposure (RME) can be uncertain and this uncertainty would be reduced by additional, better designed activity-based sampling. Until that additional actively based sampling is complete and all the pathways for that exposure identified, the selected remedies for OU1 & 2 should not be considered final.

Comment 4:

Extensive activity-based sampling, using transmission electron microscopy ("TEM") analysis to characterize the entire spectrum of exposures generated (size and type of amphibole), should be performed throughout the Libby Asbestos Site and within all OUs to determine potential cumulative exposure of residents to LA. Activity-based sampling must be specific to each OU and used to simulate likely site activities and potential exposures associated with these activities. In addition to the collection of personal samples at appropriate breathing zone heights (for children and adults as may be appropriate for the subject OU), the activity-based sampling should include surface wipe samples of protective clothing worn and equipment used by the researchers. Research in the Libby area has demonstrated a strong potential for clothing and equipment contamination among people working with and around material contaminated with LA.

This contamination may serve as a secondary source of exposure to those who work or recreate around contaminated material. In addition, family members, etc. not directly exposed to LA may be exposed while laundering contaminated clothing. Perimeter samples must be collected to document migration concurrent with the activity-based sampling. Background (control) samples must be collected, concurrent with and upwind in the same general area as the activity-based sampling, at a distance sufficient to prevent being influenced by the simulated activities. Soil moisture and wind data must be collected in conjunction with the activity-based sampling. The analytical data obtained must contain the full details on the particle size (length, width, mineral type) of all asbestos structures observed, so that these data can be used in prospective studies (including studies of low dose and childhood exposure) and cancer and non-cancer risk models. Such a sampling program will help identify all pathways and the parameters which control exposure. Until that sampling is done and analyzed vis-à-vis the remedy selected for OU 1 and 2, those remedies cannot be deemed to be final.

Comment 5:

Limited activity-based sampling has been done at OU1 and OU2. At OU1, only 8 activity-based sampling values are available, and these values may not be representative of the true long-term average exposure concentration for soil disturbances at OU1. The mean is highly uncertain and may be low. The data may underestimate exposure and risk because most of the ground was wetted to suppress dust dispersion before mowing.

Comment 6:

Activity-based sampling has shown that it is not known if all pathways of exposure are discovered and/or those that are known are not completely understood. As such, the PPs cannot be said to accomplish the goal of severing all pathways and the assessments of risks of continued exposure must be fully included in the PPs.

Comment 7:

The following sub comments address some of the inadequacies in EPA's present approach to risk assessment at the Libby Asbestos Site in general, and the PPs for OU1 and 2 in particular. These inadequacies call into question the accuracy and reliability of the data EPA relies upon to make its risk assessments.

Comment 7(a):

Uncertainty in risk assessment is increased when using dose-response information only from animal studies and dose-response information from high doses (occupational) to predict adverse health effects from low exposure, and not considering increased susceptibility of special groups within the exposed

population. Susceptible groups in Libby include children whose lungs are not fully developed until early adulthood, or immune-compromised individuals. Risk models may underestimate exposures to children because: (a) their lungs are still developing; (b) children are known to have faster breathing rates; (c) children's breathing zone is closer to the ground and thus more likely to breathe soil/dust contaminated with LA; (d) activity patterns for children may increase their airborne exposures. Children's increased levels of physical activity result in proportionally greater minute volumes, likely leading to increased dose; (e) added risk for childhood exposure relates to their longer span of life years which allows for a significant cumulative dose from low level LA exposure followed by latencies adequate to cause significant health effects.

Comment 7(b):

Current risk models may underestimate the risk associated with exposure to LA. Risk models based on working populations do not address susceptible populations or brief exposures to high levels of asbestos. The current risk models do not adequately address risks associated with low-dose exposure to the mixed LA seen in Libby. The shape of the exposure-response curve at low cumulative exposures is not known. Current risk models assume a linear relationship and the slope is largely derived from occupational cohorts with much higher exposure levels.

Comment 7(c):

Exposure estimates provided in the epidemiological reports used to derive the current risk models are often highly uncertain. The cancer unit risks derived by USEPA (1986) and USEPA (2008) are based on mortality statistics from the 1970s and, consequently, may not be applicable to populations that are exposed to asbestos today. The risk of developing cancer from an exposure to asbestos has increased as life expectancy has increased. Thus, cancer risk predications based on the current method may be underestimating risk by up to 20%.

Comment 7(d):

The current risk models do not address the risks posed by fibers less than 5 micrometers (um) in length or less than 0.25 um in diameter. Air sampling data from Libby reported by several researchers indicate that the majority of airborne fibers are less than 5 um in length when analyzed by TEM. A reference concentration for inhalation exposure to LA, including non-cancer risks of LA fibers less than 5 micrometers (um) in length and 0.25 um in diameter, must be developed and used for future sampling.

Comment 7(e):

The occurrence of non-cancer effects are a significant human health concern in the Libby community and affect a large segment of the population (18%). These

non-cancer adverse health outcomes may be more significant than cancerous effects and are not addressed by the current cancer risk models. Studies of former workers and residents provide strong evidence that exposure to LA results in an increased incidence of non-cancer adverse effects, and that these effects occur in some individuals who appear to have had only low exposure.

Comment 7(f):

Animal and in vitro studies suggest that fibers less than 5 um in length may play a role in fibrosis. EPA risk assessments based on regulated (or PCME) fibers with lengths greater than 5 um and widths greater than 0.25 um could grossly underestimate exposure to short and thin fibers and lead to uncertainties in risk estimates. Approximately 50% of the fibers seen in Libby are less than 5 um in length and 30% are less than 0.25 um in diameter. To reduce uncertainties and address the most significant health concerns in Libby, the reference concentration for inhalation exposure to LA should be based on TEM analysis, including characterization of short (< 5 um) and thin (<0.25 um) fibers, and the role these fibers play in causing non-cancer adverse health effects.

Comment 7(g):

There is a Lack of epidemiology data for the Libby Asbestos Site that must be addressed. The toxicity values (carcinogenic and non-carcinogenic) for the mix of amphiboles in LA are being derived from dose-response relationships for the first time. Dose-response information can be derived from a number of different studies which include human health effects when available as well as animal studies. It has been well established that when human health data is available, it provides the information that creates less uncertainty than when other methods are used. The National Toxicology Program (NTP) states that toxicology studies along with epidemiology studies are the best means available for identifying potential human hazards. To further reduce uncertainty in any Records of Decision in Libby, the risk of inhalation exposure to LA must be evaluated using epidemiological studies of the Libby community. Epidemiological studies, together with toxicological studies, are needed to assess the health effects of low-dose exposures to LA. These studies should include examination of family members of former mine workers, people with short-term high-dose exposures, people with long-term low-dose exposures, and children. In addition to epidemiological studies in Libby, EPA should consider recent case-control studies which provide evidence for increased mesothelioma and lung cancer risks at very low lifetime cumulative exposures to amphibole asbestos.

Comment 8:

The present data gaps in solid matrix sampling data quantification must be addressed. The current analytical methods for solid matrix sampling (i.e., soil sampling) is

insufficient for cleanup decisions. The use of polarized light microscopy (PLM) for (a) identifying concentrations of Libby amphibole in environmental media (i.e., soils); and (b) basing cleanup strategies on these results is not protective of public health. It is important to note that the 1% rule is not derived from a risk assessment or any other type of health-based analysis; therefore, it does not ensure that airborne asbestos fibers re-suspended by disturbing these soils will be below levels protective of human health. It is well established that disturbing soil containing less than 1% LA can re-suspend fibers and generate airborne concentrations that may pose a risk to public health. Analytical methods are needed that will reliably measure LA in soils at concentrations well below 1%. In recent unpublished research outside of OU3, bulk samples of ash were reported as Trace <0.5 - 1% when analyzed by TEM method EPA/600/R-93/116. When analyzed by ASTM Method D 5755-03, these same samples showed between 4 to 12 million structures per gram for fibers < 5 microns and between 4 to 6 million structures per gram for fibers  $\geq$  5 microns. The limitations of expressing asbestos concentrations in % are obvious from the above example when concentrations reported as trace contain millions of fibers per gram.

Comment 9:

The estimation of bulk asbestos content in soil at OU1 and OU2 is uncertain because the soil sampling protocol may not accurately quantify the concentration of LA. Based on the preponderance of short fibers in Libby, use of the PLM method for final clearance is not appropriate. Soil samples that are below the limit of detection by PLM techniques may show high levels of asbestos fibers by other types of microscopic techniques (e.g., scanning electron microscope (SEM) or transmission electron microscopy (TEM)). In addition, for soils samples below the limit of detection by TEM analysis there is at least a 5% chance that the true value could be higher. Given the limitations of the analytical methods for identifying and quantifying LA in soils at OU1 and OU2, it is impossible to say that the pathways of exposure have been eliminated.

Comment 10:

The present data gaps in air sampling data quantification must be addressed. First, improved air sampling and analytical methods for LA must be developed that include (a) reducing inter-operator and inter-laboratory variability of the current fiber analytical methods; (b) fiber analytical methods with improved resolution to visualize smaller diameter fibers to assure more complete fiber counts; (c) a practical analytical method to differentiate between airborne exposures to asbestiform fibers from the asbestos minerals and fiber-like cleavage fragments from their non-asbestiform analogs; (d) analytical methods to assess fiber durability; (e) evaluating the collection efficiency of LA; and (f) comparison of direct and indirect sample preparation methods.

Next, because of the variability of LA in air, estimates of mean exposure concentrations are uncertain due to random variation between samples. Consequently, a large number of

samples are required to ensure that the data are representative. In addition, risk calculations based on mean air concentrations, rather than the 95th upper confidence level (UCL), represent a source of uncertainty. The lack of a method for calculating the 95th UCL could result in an underestimation of risk. Additionally, air sampling data reported from a laboratory as non-detect are treated as zero. It is probable that some of these zero values contain LA that is not quantified. Finally, air sampling data for LA represents only a point in time that may not be representative of exposure under various activities and environmental conditions.

These limitations, together with the limited activity-based sampling at OU1 and OU2, make the proposed remedy in the PPs highly uncertain. Detailed site-specific monitoring with analyses by TEM for a more comprehensive consideration of site-specific conditions related to OU1 and OU2 is needed. Risk assessments based on estimated mean anticipated exposures in OU1 and 2 are not appropriate, and risk calculations should be based on concentrations expected for the greatest exposure scenarios anticipated in OU1 and 2.

#### Comment 11:

The present data gaps in cleanup efficacy data and elimination of exposure pathways must be addressed. Because trace levels or higher levels of LA are present in soil at OU1 and OU2 and in other areas throughout Libby, future exposure associated with disturbing on-site soil during construction or redevelopment events at these sites is a potential exposure pathway. In addition, trace levels or higher levels of LA are vulnerable to disturbance by various anthropogenic or natural activities. Consequently, residents can be potentially exposed to asbestos fibers released from asbestos-containing debris or soil due to disturbance by common human intrusive activities or natural processes (e.g., wind erosion, precipitation, and extreme changes in temperature) either now or in the future. Uncontrolled drainage of water from areas contaminated with LA may result in environmental dispersion of asbestos.

Indoor stationary air monitoring performed at varying time periods following completion of cleanup actions at specific properties in Libby showed low airborne concentrations of LA following cleanup, and the level remained low for about a year. However, at some of the homes, there appeared to be an upward trend in airborne levels of LA, suggesting the potential for re-contamination. This indicates pathways of exposure still exist after the completion of cleanup activities. EPA should base clean-up targets on activities that have been shown to produce elevated concentrations by TEM analysis. Detailed site-specific monitoring using TEM methods is needed for a more comprehensive consideration of site-specific conditions related to OU1 and OU2 to assure that exposure pathways have been eliminated.

#### Comment 12:

Under EPA's own Risk Assessment Guidance for Superfund, the Libby site conceptual model addressing overall cumulative exposure and potential health risks across all

operable units must be considered. Based on the selected remedy, the PPs for OU1 and 2 apparently assume no future exposure from OU 1 and 2 that would contribute to cumulative exposure that should be addressed in the site conceptual model. As the above comments make clear, that assumption is not justified and cumulative effects must be considered.

Comment 13:

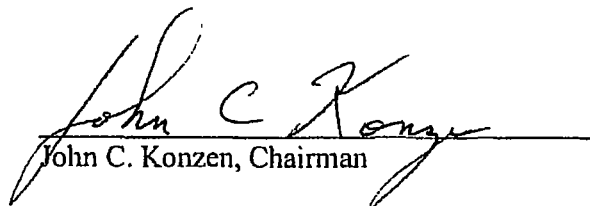
With the Libby Asbestos Site's documented public health impacts, lives are clearly at stake in the selection of the final remedy for each of the OUs. As such, a program to determine the continuing effectiveness of the final remedies should be part of any ROD issued for the Site. In the end, the ultimate test of the effectiveness and hence finality of EPA's selected remedy for the various OUs of the Libby Asbestos Site will be that remedy's impact on occurrence and pathology of asbestos-related diseases in the population. Any ROD for any of the OUs must include a long-term public health monitoring program, together with triggers for future augmentation of the remedies should the occurrence and pathologies of asbestos-related diseases not improve to a significant level. EPA must determine what those acceptable trigger levels should be and seek public comment on those levels.

Comment 14:

The Board understands that since 2007 EPA's contractors have used the "Amphitheater" area on Rainey Creek Road as a sort of transfer station in transporting LA-ladened material generated during remedial actions to their final depository in W.R. Grace's former open pit mining site. The Board also understands that a significant amount of this material has accumulated at this transfer site and that EPA is considering utilizing that transfer site as a final depository for this accumulated material and future accumulations of similar material. The Amphitheater is not well suited for such a depository and given its location near Rainey creek, such a depository will inevitably fail and be a source and new pathway for exposure to at least OU-2, if not the entire Kootenai River Valley. The ROD for OU-2 must address the safeguards that EPA will put into place to ensure that any depository placed in the areas upland from OU-2 does not recontaminate that OU or any other area.

Sincerely,

City/County Health Board for Lincoln County

  
John C. Konzen, Chairman